ATTACHMENT 2 – CONTRACT WBS MILESTONES/DELIVERABLES
HHSO100201600031C

WBS	Milestone	Deliverable	Success Criteria	Go/No-Go for initiation
BASE: Facility, Site, and Process Performance Qualification (PPQ) Readiness Activities and the Manufacture and Testing of Process Simulations				
1.1.1	Program Management	See below	See below	
1.1.1.1	Overall management, integration and coordination of all contract activities, including technical and administrative infrastructure	On-going	Milestones Met	Contract execution
	Principal Investigator (PI) responsible for program management, communication, tracking, monitoring and reporting on status and progress, and modification to the project requirements and timelines, including projects undertaken by subcontractors	Program PI	Milestones Met	Contract execution
	Project Manager(s) with responsibility for monitoring and tracking day-to-day progress and timelines, coordinating communication and project activities; cost incurred and; program management	Program PM	Milestones Met	Contract execution
	BARDA Liaison with responsibility for effective communication with the Project officer and Contracting Officer	Liaison	Effective Communication with BARDA	Contract execution
	Administrative and legal staff to provide development of compliant	Administrative & Legal Management	Timely Reporting	Contract execution

WBS	Milestone	Deliverable	Success Criteria	Go/No-Go for initiation
	subcontracts, consulting and other legal arrangements and to ensure timely acquisition of all proprietary rights, including IP rights and reporting all inventions made in the performance of the project.			
	Administrative staff with responsibility for financial management and reporting on all activities conducted by the Contractor and any subcontractor	Administrative & Financial Management	Timely Reporting	Contract execution
1.1.1.2	Program Management Deliverables	See Below	See Below	
	Program Review Meetings	Regularly scheduled meetings with subcontractors to discuss program progress and updates	Meeting conducted	Contract Execution
	Bi-weekly Teleconferences	Teleconferences with BARDA on a bi-weekly basis	Meetings conducted	Contract Execution
	Submit Updated Integrated Master Schedule (IMS)	Updated IMS Submitted	IMS Accepted	Subcontractor COA Execution + 180
	Submit Updated Integrated Master Plan (IMP)	Updated IMP Submitted	IMP Accepted	Subcontractor COA Execution + 180 days
	Submit and Maintain Program	Updated Program	Acceptance of	Subcontractor

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	Management Plan	Management Plan	PMP	COA Execution + 90 days
	Submit and Maintain Product Development Plan	IPDP input provided	IPDP input accepted	Subcontractor COA Execution + 90 days
	Subcontractor Management	Bi-weekly technical and program management meetings with the subcontractors	Documentation/ reporting on-time and complete.	Contract Execution
	Financial Management, Accounting, Reporting	Monthly financial reports	Report accepted, Payment received	Subcontractor COA Execution + 180 days
	Decision Gate Reporting	Reports created	Report accepted	Contract Execution
	Submit and Maintain Risk Management Plan	Updated Risk Management Plan and Risk Assessments	Plan and Assessments accepted	Subcontractor COA Execution + 90 days
	Submit and Maintain Quality Management Plan	Updated Quality Plan	Plan accepted	Subcontractor COA Execution + 90 days
	Performance Measurement Baseline Review (PMBR)	PMBR Meeting	Program baselines agreed and accepted	COA Execution + 180 days
	Deviation Request	Deviation report	Report accepted	Contract

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				Execution
	Monthly and Annual Reporting	Monthly/Annual progress reports filed on the 25th day of each month	Reports filed to eRoom	Contract Execution
	Data Management	Updated DM systems/procedures (as required)	Systems/procedures accepted	Contract Execution
1.1.1.3	Long term Storage and Stability Testing, 90 Roller Bottle Drug Product Lots Produced under Contract HHS010020150002c	Controlled storage and Stability data on original BARDA lots to 60 months after manufacture of DP	Storage and Stability reports accepted	Contract Execution
1.1.2	Process Performance Qualifications (PPQ) and Site Readiness Activities	See below	See below	
1.1.2.1	(b)(4)			
1.1.2.2				
1.1.2.3				

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WBS	Milestone	Deliverable	Success Criteria	Go/No-Go for initiation
1.1.2.4	(b)(4)			
1.1.3	Manufacture and Testing of Process Simulations	See below	See below	
	(b)(4)			
1.1.4	Regulatory Support Activities	BPS and subcontractor support of regulatory activities	Engagement with FDA and EMA on non-CMC portions on	Preparation of non-CMC portions of the BLA and

WBS	Milestone	Deliverable	Success Criteria	Go/No-Go for initiation
			the BLA and MMA	MMA.
1.1.5	Non-Clinical: Reproductive Toxicology Studies	See below	See below	
1.1.5.1	In Life Study	Vaccination, monitoring, procedures, and blood collection as defined in the protocol	Successful completion of study	Study completion
1.1.5.2	Sample Testing	Testing of samples from the study as defined in the protocol	Testing complete	Testing complete
1.1.5.3	Draft and Final Report generated	Un-audited draft report and final report	Final report complete	Report accepted
1.1.6	Clinical Study: Immunogencity for PREVAIL and PREPARE Studies	See below	See below	
1.1.6.1	GP-ELISA and PRNT of PREVAIL Study Samples	GP-ELISA and PRNT of PREVAIL Study Samples	PREVAIL study testing complete	Samples ready and available for testing
1.1.6.2	GP-ELISA or PRNT Testing of PREVAIL Long Term Follow Up Samples	GP-ELISA or PRNT PREVAIL Study Samples	PREVAIL study testing complete	Samples ready and available for testing
1.1.6.3	GP-ELISA or PRNT of PREPARE study samples	GP-ELISA or PRNT of PREPARE study samples	PREPARE study testing complete	Samples ready and available for testing
Option 1: Manufacturing and Testing of PPQ lots, BLA Preparation and Pre-PAI Activities				

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WBS	Milestone	Deliverable	Success Criteria	Go/No-Go for initiation
2.1	Program Management	See 1.1 Above	See 1.1 Above	Option exercised
2.2	Manufacturing and Testing of Process Performance Qualification (PPQ) Lots	See below	See below	
	(b)(4)			

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WBS	Milestone	Deliverable	Success Criteria	Go/No-Go for initiation
	(b)(4)			

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WBS	Milestone	Deliverable	Success Criteria	Go/No-Go for initiation
	(b)(4)			
2.3	BLA Preparation and Pre-PAI Activities	See below	See below	
	Regulatory Meetings Held	Meeting minutes	Minutes accepted	Request to the FDA

WBS	Milestone	Deliverable	Success Criteria	Go/No-Go for initiation
	Pre-Approval Audit	Audit report	Report accepted; remediation plan accepted with majors completed.	FDA requested
Option 2: Clinical: Pediatric Clinical Trial				
3.1	Program Management	See 1.1 Above	See 1.1 Above	Option exercised
3.2	Design and Implementation for Phase II Safety and Immunogenicity Clinical Trial in Children	See below	See below	
	(b)(4)			

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WBS	Milestone	Deliverable	Success Criteria	Go/No-Go for initiation
	(b)(4)			
3.3	Clinical Trial Execution			
	(b)(4)			

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WBS	Milestone	Deliverable	Success Criteria	Go/No-Go for initiation
		(b)(4)		
Option 3: Additional Process Simulations and Manufacturing of PPQ lots				
4.1	Program Management	See 1.1 Above	See 1.1 Above	Option exercised
4.2	(b)(4)			
4.3				